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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,683	12/08/2003	Art Bertolero	021063-000510US	3268

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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	**PAPER NUMBER**
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,683	BERTOLERO ET AL.	
	Examiner	Art Unit	
	CHRISTINE D. HOPKINS	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-29 and 32-68* is/are pending in the application.

4a) Of the above claim(s) *24-29,35,36,46-52 and 57-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23,32-34,37-45,53-56 and 62-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 October 2007 has been entered. Claims 20-29 and 32-68 are now pending, while claims 24-29, 35, 36, 46-52 and 57-61 remain withdrawn from consideration. The Examiner acknowledges the amendments to claims 20, 41, 45 and 67.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 20-23, 32-34, 37, 39, 40 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Paolitto et al. (U.S. Pub. No. 2003/0010346). Paolitto et al. (hereinafter Paolitto) teach a surgical apparatus and procedure for performing surgery

on a beating heart via percutaneous approach. Regarding claims 20-23 and 40, Paolitto discloses a heart stabilizing device **20** and a heart positioning device **30**. A tissue retractor **40** provides access to the patient's heart through an incision [0102]. Heart stabilizing device **20** engages a surface of the beating heart through suction imposed by a negative pressure source through a barb fitting "port" [0106]. It is noted that Paolitto teaches that multiple cannulae may be inserted for access to the thoracic cavity of the patient. For instance, one access cannula may be deployed to access the left pleural space, and another may be deployed to access the right plural space, thus allowing the use of multiple instruments within a first, second and third incision [0195]. A first coupling device and second coupling device are interpreted as cannulae **10** (one provided at two separate incisions) for accessing the thoracic cavity. Each cannula constitutes an elongated shaft (see Fig. 3A) having a proximal end and distal end, with a means for coupling with the heart stabilizing device and heart positioning device. Such a means is collet **182** of cannula **10** (or coupling device) for coupling with either a heart stabilizing device or the heart positioning device [0072]. The coupling device further comprises at least one "flexible, rigidifying portion" interpreted as permanent weir **130**. Permanent weir **130** extending around the perimeter of access cannula **10** (or "elongate shaft") is preferably rigid, but may also be made from a more flexible biocompatible polymeric material [0055]. Furthermore, regarding the "closed section" of the permanent weir, it is noted that the specification does not provide any particular definition for such, nor does a drawing may reference to such. Therefore, since "closed" is defined as having, or forming a boundary or barrier, and the weir is referred

to as "an anatomic barrier engaging means" [0055], Paolitto is considered to anticipate "one flexible, rigidifying portion having a closed section" as recited in claim 20.

Regarding claims 32-34, a flexible arm **50** couples the first and second coupling devices with at least one stable object, such as surgical table **3** [0058]. The flexible arm enables re-positioning and re-orientation of the cannula or "coupling device" [0064]. The first and second arms are further capable of being "rigidified" after coupling with a stable object via a clamp **570** [0058].

Paolitto teaches a tissue retractor **40** having a frame (see Fig. 4) for movably holding two retractor blades **410** for retracting an incision. A lever **430** engages handle **461** to "crank" the retractor blades and thus retract the tissue for subsequent access to the patient's interior anatomy, in accordance with claims 37 and 39.

Regarding claim 63, an "actuation device," or tightening member **181** can tighten the coupling means **182** to the surgical tool **20** and loosen the coupling means from the surgical tool.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 41-43, 45, 53-54, 56 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paolitto et al. (U.S. Pub. No. 2003/0010346) Regarding claims 41-43 and 45, Paolitto discloses the invention as claimed, see rejection supra; however Paolitto does not disclose expressly that the surgical tool (heart stabilizing device/heart positioning device) comprises a ball for coupling with an elongate coupling member (cannula). Instead, Paolitto indicates that a surgical tool and elongate coupling member comprise means for coupling in the form of collet **182** of cannula **10** (or coupling device) and socket surface **119** ([0074] and Fig. 14A). Applicant further provides that any suitable combination allowing the coupling device to attach to the surgical tool is contemplated. One such mechanism of attachment includes a collet and socket arrangement [0034]. Moreover, Paolitto teaches an alternate embodiment whereby the surgical tool, with one or more integral spherical bosses ("ball") along its longitudinal axis, may be inserted into joint **180** ("means for coupling with the surgical tool") of the coupling member [0075]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a collet and socket arrangement because Applicant has not disclosed that a ball/collet, clamp/rail or any other various attachment mechanism indicated in the specification provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Paolitto's socket/collet arrangement or spherical boss/joint arrangement and applicant's invention, to perform equally well with either the arrangements taught by Paolitto or the claimed ball arrangement because both would perform the same function of enabling an attachment between a surgical tool and

cannula that allows introduction of a surgical tool to a patient incision and manipulation of the tool by the surgeon. Therefore, at the time of the invention it would have been prima facie obvious to modify Paolitto to obtain the invention as specified in claim 41 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Paolitto.

An "actuation device," or tightening member **181** can tighten the coupling means **182** to the surgical tool **20** and loosen the coupling means from the surgical tool, also in accordance with claim 41.

Further regarding claims 42-43, 45, and claims 53-54, 56 and 65, Paolitto discloses a heart stabilizing device **20** and a heart positioning device **30**. A tissue retractor **40** provides access to the patient's heart through an incision [0102]. Heart stabilizing device **20** engages a surface of the beating heart through suction imposed by a negative pressure source through a barb fitting "port" [0106]. It is noted that Paolitto teaches that multiple cannulae may be inserted for access to the thoracic cavity of the patient. For instance, one access cannula may be deployed to access the left pleural space, and another may be deployed to access the right plural space, thus allowing the use of multiple instruments within a first, second and third incision [0195]. A first coupling device and second coupling device are interpreted as cannulae **10** (one provided at two separate incisions) for accessing the thoracic cavity. Each cannula constitutes an elongated shaft (see Fig. 3A) having a proximal end and distal end, with a means for coupling with the heart stabilizing device and heart positioning device. Such a means is collet **182** of cannula **10** (or coupling device) for coupling with either a

heart stabilizing device or the heart positioning device [0072]. The coupling device further comprises at least one "flexible, rigidifying portion" interpreted as permanent weir **130**. Permanent weir **130** extending around the perimeter of access cannula **10** (or "elongate shaft") is preferably rigid, but may also be made from a more flexible biocompatible polymeric material [0055].

6. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Daniel et al. (U.S. Pub. No. 2002/0068855). Paolitto discloses the invention as claimed, see rejection supra; however Paolitto does not expressly disclose a retracting blade having nerve protection means. Daniel et al. (hereinafter Daniel) teach a system and apparatus for manipulating a tissue structure within a body cavity, such as the heart, by retracting an outer portion enclosing the tissue. Regarding claim 38, Daniel teaches a retractor used with an atraumatic tissue-engaging surface **220**, wherein the tissue-engaging surface **220** comprises a rigid plate and a biocompatible elastomeric cushion engaging the heart directly ([0065] and [0069]). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have fitted a retracting device as taught by Paolitto with an elastomeric, biocompatible portion as suggested by Daniel such that the portion of the device engaging the tissue to be retracted imparts as little stress to the heart tissue as possible and protects the anatomy (including that of surrounding nerves) from damage as a result of the invasive nature of the surgical instruments utilized.

7. Claims 44 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Houser et al. (U.S. Pub. No. 2003/0060685). Paolitto discloses the invention as claimed, see rejection supra; however Paolitto does not teach inflating a tissue contacting surface of the heart stabilizing or positioning member. Houser et al. (hereinafter Houser) teach a surgical instrument for contacting and stabilizing tissue of the heart. Regarding claims 44 and 55, Houser teaches a heart stabilizing or positioning member **100** having a tissue contacting surface **120**. The contacting section may be configured to provide a variety of atraumatic surfaces, as well as ways to prevent slippage and invoke immobilization of the heart. Houser teaches a member or "port" to supply vacuum, a stream of fluid, or an inflatable medium to abut the contacting section against the surface of the heart [0113]. Furthermore, Houser teaches the introduction of an inflation medium through the same conduit for supplying vacuum, which immobilizes the heart (as in the instant application). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided an inflation medium as suggested by Houser to a heart stabilizing or positioning member as taught by Paolitto such that minimal damage is imparted to the sensitive cardiac tissue.

8. Claims 62, 64 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Peng et al. (U.S. Pub. No. 2003/0009080). Paolitto discloses the invention as claimed, see rejection supra; however Paolitto does not expressly disclose a flexible arm coupled with the first coupling device, whereby the flexible arm can be rigidified by applying

suction. Peng et al. (hereinafter Peng) teaches an organ manipulator including at least one suction member. Regarding claims 62, 64 and 66-68, Peng teaches a flexible arm **4** having both a rigid and flexible state and "a closed section" (Fig. 1), and a suction line **5** which acts to rigidify the flexible arm **4** [0070]. Paolitto similarly teaches a rigid arm **540** for coupling with the first coupling device [0058]. Furthermore, Peng discloses that multiple arms may be incorporated for positioning the suction member, constituting a "second coupling device" and "second flexible arm" (Fig. 14).

Further regarding claims 66 and 68, Paolitto teaches a retractor device **40**, a heart stabilizing device **20** comprising a tissue contacting surface, a suction aperture [0106] and a complementary coupling means **119**. A first coupling device **10** comprises an elongate shaft having a proximal and distal end, a distal coupling means **180** that can be tightened or loosened by an actuation device **181** relative to the complementary coupling means **119** ([0073]-[0074]). A first arm **540** is coupled with the first coupling device via a clamp **510** (Fig. 7 and [0058]). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided a rigid arm as taught by Paolitto with flexible properties as suggested by Peng in order to stabilize the suction member on the heart.

Response to Arguments

9. Applicant's arguments filed 15 October 2007 with respect to the rejection of claims 20-23, 32-34, 37, 39, 40 and 63 under 35 U.S.C. 102(e) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) have been fully considered but are moot in view of the new

rejection under 35 U.S.C. 102(e) to Paolitto et al. (U.S. Pub. No. 2003/0010346). However, Applicant contends that Paolitto does not describe a rigidifying portion that has a closed section. This argument is not persuasive for at least the reason presented above noting that the specification of the instant application does not provide any particular definition for "a closed section" of the rigidifying portion, nor is such indicated within the drawings. Therefore, since "closed" is defined as having, or forming a boundary or barrier, and the weir is referred to as "an anatomic barrier engaging means" [0055], Paolitto is considered to anticipate "one flexible, rigidifying portion having a closed section" as recited in claim 20.

10. Applicant's arguments filed 15 October 2007 with respect to the rejection of claims 41-43, 45, 53-54, 56 and 65 under 35 U.S.C. 102(e) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) have been fully considered but are moot in view of the new rejection under 35 U.S.C. 103(a) to Paolitto et al. (U.S. Pub. No. 2003/0010346) as a design choice, see rejection supra.

11. Applicant's arguments filed 15 October 2007 with respect to the rejection of claim 38 under 35 U.S.C. 103(e) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Daniel (U.S. Pub. No. 2002/0068855) have been fully considered but are moot in view of the new rejection under 35 U.S.C. 103(a) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Daniel (U.S. Pub. No. 2002/0068855). However, Applicant contends that Daniel does not remedy the deficiency of Paolitto because Daniel discusses an endoscopic retraction system. This argument is not persuasive because

the deficiency of Paolitto lies within nerve protection means. Since Daniel teaches a system that likewise manipulates tissue structures within a body cavity, Daniel is thus found to provide sufficient means to remedy the deficiency of Paolitto.

12. Applicant's arguments filed 15 October 2007 with respect to the rejection of claims 44 and 55 under 35 U.S.C. 103(a) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Houser et al. (U.S. Pub. No. 2003/0060685) have been fully considered but are moot in view of the new grounds of rejection presented above citing Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Houser et al. (U.S. Pub. No. 2003/0060685). However, Applicant contends that Houser discusses a shape memory tissue stabilizer, but does not remedy the deficiency of Paolitto. This argument is not persuasive because the deficiency of Paolitto lies within inflating a tissue contacting surface of a heart immobilization structure. Houser teaches such immobilization via similar mechanisms as Paolitto (suction). The immobilization structure of Paolitto is also of atraumatic construction. Therefore, providing an inflation medium as suggested by Houser would enhance the atraumatic features of the heart immobilization structure of Paolitto.

13. Applicant's arguments filed 15 October 2007 with respect to the rejection of claims 62, 64, and 66-68 under 35 U.S.C. 103(a) citing Paolitto et al. (U.S. Pub. No. 2003/0010346) in view of Peng (U.S. Pub. No. 2003/0010346) have been fully considered but are moot in view of the new rejection under 35 U.S.C. 103(a) to Paolitto

et al. (U.S. Pub. No. 2003/0010346) in view of Peng (U.S. Pub. No. 2003/0010346) taking into consideration the amended subject matter, see rejection supra.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
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Examiner
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